PI 1094208



# THE UNITED STATES OF AMERICA

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**November 17, 2003**

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**APPLICATION NUMBER:** *60/416,058*
**FILING DATE:** *October 04, 2002*
**RELATED PCT APPLICATION NUMBER:** *PCT/US03/31640*

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PRIORITY DOCUMENT

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N. Woodson

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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. EV183769715US

## INVENTOR(S)

| Given Name (first and middle [if any]) | Family Name or Surname | Residence (City and either State or Foreign Country) |
|---|---|---|
| Michael | Primavera | 312 Foxwood Lane<br>Milford, CT 06460 |

☑ *Additional inventors are being named on the 1 separately numbered sheets attached hereto*

**TITLE OF THE INVENTION (280 characters max)**

SURGICAL SUTURING APPARATUS WITH MEASUREMENT STRUCTURE

*Direct all correspondence to:* **CORRESPONDENCE ADDRESS**

☐ Customer Number [ ] → *Place Customer Number Bar Code Label here*

OR *Type Customer Number here*

| | | | | | |
|---|---|---|---|---|---|
| ☑ Firm or Individual Name | Chief Patent Counsel | | | | |
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| Address | 150 Glover Avenue | | | | |
| City | Norwalk | State | Connecticut | ZIP | 06856 |
| Country | US | Telephone | (203) 845-4603 | Fax | |

**ENCLOSED APPLICATION PARTS *(check all that apply)***

☑ Specification *Number of Pages* 9 pgs.
☑ Drawing(s) *Number of Sheets* 7 pgs.
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number
☐ Other (specify)

**METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT**

☐ Applicant claims small entity status. See 37 CFR 1.27.
☑ A check or money order is enclosed to cover the filing fees
☑ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 50-2140
☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE AMOUNT ($): $160.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government

☐ No
☐ Yes, the name of the U.S Government agency and the Government contract number are: _____

*Respectfully submitted,*

SIGNATURE David M. Carter

Date 10 / 04 / 02

TYPED or PRINTED NAME David M. Carter

REGISTRATION NO. *(if appropriate)* 30,949

TELEPHONE (631) 501-5700

Docket Number: 2865PRO

CERTIFICATION UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence and the documents referred to as enclosed are being deposited with the United States Postal Service on date below in an envelope as "Express Mail Post Office to Addressee" Mail Label Number EV183769715US addressed to: Assistant Commissioner for Patents, Box Provisional Application, Washington, D.C. 20231.

Dated: October 4, 2002

David M. Carter

David M. Carter

# PROVISIONAL APPLICATION COVER SHEET
## Additional Page

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| INVENTOR(S)/APPLICANT(S) | | |
|---|---|---|
| Given Name (first and middle [if any]) | Family or Surname | Residence (City and either State or Foreign Country) |
| Kevin | Clair | 164 Bibbins Road<br>Easton, CT 06612 |

Number 2 of 2

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# FEE TRANSMITTAL for FY 2002

*Patent fees are subject to annual revision*

| TOTAL AMOUNT OF PAYMENT | ($) 160.00 |
|---|---|

| Complete if Known | |
|---|---|
| Application Number | |
| Filing Date | October 4, 2002 |
| First Named Inventor | Michael Primavera et al. |
| Examiner Name | |
| Group Art Unit | |
| Attorney Docket No. | 2865PRO (203-3484) |

## METHOD OF PAYMENT (check one)

1. [X] The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to

Deposit Account Number: 50-2140

Deposit Account Name: CARTER, DELUCA, FARRELL & SCHMIDT LLP

[X] Charge Any Additional Fee Required Under 37 CFR 1 16 and 1 17

[ ] Applicant claims small entity status See 37 CFR 1 27

2. [X] Payment Enclosed:

[X] Check [ ] Credit card [ ] Money Order [ ] Other

## FEE CALCULATION

### 1. BASIC FILING FEE

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 101 | 740 | 201 | 370 | Utility filing fee | |
| 106 | 330 | 206 | 165 | Design filing fee | |
| 107 | 510 | 207 | 255 | Plant filing fee | |
| 108 | 740 | 208 | 370 | Reissue filing fee | |
| 114 | 160 | 214 | 80 | Provisional filing fee | $160.00 |

SUBTOTAL (1) ($) 160.00

### 2. EXTRA CLAIM FEES

| | Extra Claims | | Fee from below | Fee Paid |
|---|---|---|---|---|
| Total Claims | | -20** = | X $18 | = $0 |
| Independent Claims | | - 3** = | X $84 | = 0 |
| Multiple Dependent | | | $280 | = 0 |

**or number previously paid, if greater; For Reissues, see below

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description |
|---|---|---|---|---|
| 103 | 18 | 203 | 9 | Claims in excess of 20 |
| 102 | 84 | 202 | 42 | Independent claims in excess of 3 |
| 104 | 280 | 204 | 140 | Multiple dependent claim, if not paid |
| 109 | 84 | 209 | 42 | ** Reissue independent claims over original patent |
| 110 | 18 | 210 | 9 | ** Reissue claims in excess of 20 and over original patent |

SUBTOTAL (2) ($) 0.00

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

| Large Entity Fee Code | Large Entity Fee ($) | Small Entity Fee Code | Small Entity Fee ($) | Fee Description | Fee Paid |
|---|---|---|---|---|---|
| 105 | 130 | 205 | 65 | Surcharge - late filing fee or oath | |
| 127 | 50 | 227 | 25 | Surcharge - late provisional filing fee or cover sheet | |
| 139 | 130 | 139 | 130 | Non-English specification | |
| 147 | 2,520 | 147 | 2,520 | For filing a request for *ex parte* reexamination | |
| 112 | 920* | 112 | 920* | Requesting publication of SIR prior to Examiner action | |
| 113 | 1,840* | 113 | 1,840* | Requesting publication of SIR after Examiner action | |
| 115 | 110 | 215 | 55 | Extension for reply within first month | |
| 116 | 400 | 216 | 200 | Extension for reply within second month | |
| 117 | 920 | 217 | 460 | Extension for reply within third month | |
| 118 | 1,440 | 218 | 720 | Extension for reply within fourth month | |
| 128 | 1,960 | 228 | 980 | Extension for reply within fifth month | |
| 119 | 320 | 219 | 160 | Notice of Appeal | |
| 120 | 320 | 220 | 160 | Filing a brief in support of an appeal | |
| 121 | 280 | 221 | 140 | Request for oral hearing | |
| 138 | 1,510 | 138 | 1,510 | Petition to institute a public use proceeding | |
| 140 | 110 | 240 | 55 | Petition to revive - unavoidable | |
| 141 | 1,280 | 241 | 640 | Petition to revive - unintentional | |
| 142 | 1,280 | 242 | 640 | Utility issue fee (or reissue) | |
| 143 | 460 | 243 | 230 | Design issue fee | |
| 144 | 620 | 244 | 310 | Plant issue fee | |
| 122 | 130 | 122 | 130 | Petitions to the Commissioner | |
| 123 | 50 | 123 | 50 | Processing fee under 37 CFR 1 17(q) | |
| 126 | 180 | 126 | 180 | Submission of Information Disclosure Stmt | |
| 581 | 40 | 581 | 40 | Recording each patent assignment per property (times number of properties) | |
| 146 | 740 | 246 | 370 | Filing a submission after final rejection (37 CFR § 1 129(a)) | |
| 149 | 740 | 249 | 370 | For each additional invention to be examined (37 CFR § 1 129(b)) | |
| 179 | 740 | 279 | 370 | Request for Continued Examination (RCE) | |
| 169 | 900 | 169 | 900 | Request for expedited examination of a design application | |

Other fee (specify) _____

* Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

| SUBMITTED BY | | | | Complete (if applicable) | |
|---|---|---|---|---|---|
| Name (Print/Type) | David M. Carter | Registration No (Attorney/Agent) | 30,949 | Telephone | (631) 501-5700 |
| Signature | David M. Carter | | | Date | October 4, 2002 |

CERTIFICATION UNDER 37 C.F.R. § 1.10

I hereby certify that this correspondence and the documents referred to as enclosed are being deposited with the United States Postal Service on date below in an envelope as "Express Mail Post Office to Addressee" Mail Label Number EV183769715US addressed to: Assistant Commissioner for Patents, Box Provisional Application, Washington, D.C. 20231.

Dated: October 4, 2002

David M. Carter

# SURGICAL SUTURING APPARATUS WITH MEASUREMENT STRUCTURE

## BACKGROUND

### 1. Technical Field

The present disclosure relates generally to surgical instrumentation and, more particularly, to surgical instrumentation having measuring apparatus for use in endoscopic or laparoscopic surgical procedures.

### 2. Description of Related Art

Endoscopic or laparoscopic procedures are characterized by the use of an elongated cannula structure having a relatively small diameter with a proximal and distal end. The distal end of the cannula is passed through the surrounding tissue into the body cavity wherein the surgical procedure or examination is to be effected, thus providing a conduit for the insertion of surgical instrumentation. A plurality of cannula structures may be used to allow operation of a variety of instruments simultaneously during a given procedure. For example, one cannula may provide a conduit for an endoscope for vision and illumination within the operative cavity while the other cannulas may provide conduits for control of specialized surgical instruments designed for performing specific procedural functions.

Many surgical procedures call for placing stitches through tissue, a procedure traditionally accomplished by hand. Laparoscopic suturing presents a particularly challenging task, because it must be accomplished using remote instrumentation through a port that typically averages between five and ten millimeters. Instruments for facilitating laparoscopic suturing are disclosed in United States Patent No. 5,478,344, issued December 26, 1995, to Stone et al., which is incorporated herein in its entirety by reference. The Stone et al. patent discloses a surgical suturing apparatus capable of passing a surgical needle, having a length of suture

attached thereto, back and forth between its jaws to suture tissue. In addition, it discloses methods of using the apparatus to suture tissue.

Other laparoscopic suturing instruments are also available in the marketplace. For example, United States Patent No. 5,690,653, issued November 25, 1997, to Richardson et al. discloses a suturing device that includes an elongated tubular shaft having a needle disposed at the distal end and a suture that extends rearwardly from the needle along the longitudinal plane of the shaft as well as a method of using the device.

However, while the above-mentioned devices are valuable for laparoscopic suturing, none of the above-mentioned devices includes structure or discloses a method that facilitates measurement of the length of suture material while the device is in the body cavity. Therefore, a need exists for a suturing apparatus that maintains the advantages of laparoscopic suturing and incorporates a suture material measurement structure.

## SUMMARY

Various measuring structures are provided for use with a number of different laparoscopic surgical instruments. The measuring structures are disposed on the apparatus for determining the length of a suture or determining the amount of suture material remaining when using the apparatus. Preferably, the measuring structure is an integral part of the laparoscopic instrument and is disposed at the distal end of the instrument for accurate measurement of the suture. Alternatively, the measuring structure is included in a kit that can be used with a number of different laparoscopic instruments. In either embodiment, the measuring structure has a number of graduations showing the selected units of measure. Further still, the measuring structure can be positioned such that the graduations are only visible from one vantage point. However, in a preferred embodiment, the measuring structure will be disposed so that it covers

the outer perimeter of the surgical instrument substantially in its entirety. In this embodiment, the graduations of the measuring structure will be visible to the surgeon from most any vantage point enabling the surgeon to obtain a measurement without undue manipulation of the laparoscopic instrument. These together with other advantages will become apparent from the details of construction and operation as more fully hereinafter described.

**BRIEF DESCRIPTION OF THE DRAWINGS**

Various embodiments are disclosed herein with reference to the drawings wherein;

FIG. 1 is a perspective view of the distal end of a surgical suturing apparatus illustrating one embodiment of the measuring structure;

FIG. 2 is a perspective view of the distal end of the suturing apparatus of FIG. 1 showing a grasping instrument holding the suture along the scale;

FIG. 3 is a plan view of a scale;

FIG. 4 is a side view of the distal end of the tubular housing of FIG. 1 illustrating the attached scale of FIG. 3 measuring the length of suture material;

FIG. 5 is a side view of the distal end of the tubular housing of FIG. 1 illustrating the attached scale of FIG. 3 measuring a differing length of suture material;

FIG. 6 is a perspective view of the distal end of different surgical suturing apparatus illustrating the measuring structure;

FIG. 7 is a perspective view of the distal end of another laparoscopic surgical apparatus illustrating the measuring structure; and

FIG. 8 is a perspective view of a surgical grasping instrument illustrating the measuring structure.

## DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to the drawings and in particular to FIG. 1, there is shown a suturing apparatus generally indicated by reference numeral 10, which has an elongated tubular housing or body portion 12, and two jaws (or jaw elements) 14 and 16. A needle 18 is removably attached to jaw 14 at the distal end of suturing apparatus 10. A measuring structure including a scale 100 is disposed on the distal portion of tubular housing 12.

Still referring to FIG. 1, scale 100 is preferably disposed along a portion of tubular housing 12 such that scale 100 is adjacent to the distal end and extends longitudinally along tubular housing 12. A plurality of graduations 110 are disposed on scale 100 and are uniformly spaced apart along the longitudinal axis of scale 100. Graduations 110 may be marked with Roman numerals, Greek letters, or other suitable symbols of indicia. Preferably, graduations 110 are marked with Arabic numerals so that the units of measure are readily ascertainable. Although graduations 110 are shown in centimeters, the actual units of measure may be changed to suit the user's needs without departing from the scope of the disclosure (e.g. inches, millimeters, decimeters, etc.).

As shown in FIGS. 1 and 2, graduations 110 on scale 100 are generally in the same viewing plane as needle 18. Placing needle 18 and graduations 110 in the same viewing plane allows the surgeon using suturing apparatus 10 to observe scale 100, needle 18 and a suture 20 simultaneously. However, during endoscopic surgery, the surgeon's field of view is limited by the endoscope and suture 20 may not lie in the field of view of the endoscope. It is preferred that graduations 110 be visible to the surgeon regardless of the physical orientation of the surgical instrument. Therefore, the lateral dimensions of scale 100 and graduations 110 are such that graduations 110 cover a large enough area on tubular housing 12 so that graduations 110 are

visible to the surgeon regardless of the orientation of the surgical instrument. Changing the size of scale 100 and graduations 110 does not alter the accuracy of the instrument since graduations 110 are still uniformly spaced apart, but allows graduations 110 to be visible in more than one plane of view. For example, graduations 110 may encompass approximately up to 90 degrees of the surface of tubular housing 12 as shown in FIG. 1. In addition, more than one scale may be disposed on a surgical instrument such as disposing a number of scales laterally on tubular housing 12. When a number of scales are disposed laterally in this fashion, the scales may be contiguous or may be transversely spaced apart. Preferably, graduations 110 will extend circumferentially about tubular housing 12 up to and including 360 degrees of the surface.

Scale 100 and graduations 110 are shown in the FIGS. being disposed on tubular surgical instruments for illustrative purposes only. It is within the scope of this disclosure for scale 100 and graduations 110 to be disposed on instruments that have regular or irregular polygonal shapes. With instruments that have regular or irregular polygonal shapes, graduations 110 may be disposed on one or more surfaces of the polygon, alternating surfaces of the polygon or all surfaces of the polygon depending on the particular instrument and its application.

A more detailed view of scale 100 with graduations 110 is shown in FIG. 3. Although scale 100 is shown having a range of 5-20 centimeters, other ranges are entirely within the scope of the present disclosure. The selected range of scale 100 and units of graduations 110 are determined by the user's requirements. In the present example of 5-20 centimeters, scale 100 has an accuracy of +/- 0.6 centimeters. In this figure, the scale 100 is using one (1) unit graduations commencing with the numeral five (5). It is within the scope of the disclosure that scale 100 could be designed to include graduations 110 representing less than one (1) unit (i.e. ½ unit) or units greater than one (1) unit (e.g. 1 ½ , 2, or 5). The number of units represented by

each graduation 110 is not limited to what is disclosed here, but is to be determined by the ultimate application of the scale 100. In addition, graduations 110 are illustrated in centimeters, the actual units of measure may be changed to suit the user's needs without departing from the scope of the disclosure (e.g. inches, millimeters, decimeters, etc.).

FIGS. 4 and 5 depict the distal end of tubular housing 12 of suturing apparatus 10. Scale 100 is disposed adjacent and posterior to the support 52. In FIG. 4, scale 100 shows that approximately twenty (20) centimeters of suture 20 are attached to needle 18. In FIG. 5, one or more sutures have been sewn leaving approximately ten (10) centimeters of suture 20 available for use. The accuracy of scale 100 is +/- 0.6 graduations, or in the present example +/- 0.6 centimeters. The ability of the surgeon to discern the remaining length of suture 20 easily and readily enables the surgeon to predict the number of sutures that can be safely sewn before it is necessary to remove suturing apparatus 10 for reloading.

Although suturing apparatus 10 will be periodically removed for reloading, the addition of attached scale 100 permits the surgeon to minimize the number of reloading operations that must be performed. This enables the surgeon to minimize the time of the procedure and minimize the quantity of suture material used. Scale 100 is envisioned to be incorporated into the structure of tubular housing 12 during the manufacturing process wherein graduations 110 would be etched, embossed or otherwise permanently part of tubular housing 12.

Alternately, scale 100 and graduations 110 could be supplied as part of a kit to allow the surgeon to select the units of measurement and the length of scale 100. Furthermore, supplying scale 100 in kit form allows existing owners of suturing apparatus 10 to take full advantage of this disclosure without the need to purchase new suturing apparatuses 10. For example, the kit could include scales 100 having different ranges of graduations, different units of measurement,

or numerous combinations of the preceding depending on the demands of the marketplace. In one embodiment, each scale 100 that is supplied as part of a kit would has an adhesive backing for attachment to tubular housing 12 and that this adhesive backing would securely attach scale 100 to tubular housing 12 to alleviate any concerns about scale 100 becoming dislodged in the cavity during the endoscopic procedure.

However, the preferred method for attaching scale 100 is to place scale 100 on heat shrinkable tubing. During preparation for surgery, the heat shrinkable tubing would be placed over the distal end of the surgical instrument and moved towards the proximal end along the longitudinal axis of the instrument. Once the heat shrinkable tubing is properly positioned, a flameless heat source is applied uniformly to the heat shrinkable tubing. Once the heat shrinkable tubing has shrunk to its designed size, and conformed to the shape of the surgical instrument, the heat source is removed leaving the surgical instrument with a measuring apparatus properly positioned for use. Further still, the kit include may an assembly template to ensure that scale 100 is disposed along tubular housing 12 with the proper orientation and proper longitudinal positioning. This is essential so that each suturing apparatus 10 will produce the same measurements and ensure highly repeatable results for the surgeon.

Referring to FIG. 2, scale 100 is disposed along the longitudinal axis of tubular housing 12 and posterior to jaws 14, 16. During laparoscopic suturing, the surgeon closes jaws 14, 16 about the tissue, forcing needle 18 and suture 20 to pierce the tissue. Next, the surgeon then takes a grasping tool 150 and grabs the distal end of suture 20 with grasping tool 150. Using grasping tool 150, the surgeon holds suture 20 taut against the surface of scale 100 thereby allowing the surgeon to measure the length of suture 20. By holding suture 20 taut against scale 100, the surgeon is able to read the remaining length of suture 20 accurately.

Turning to FIG. 6, the distal end of a different surgical suturing apparatus 210 is illustrated. This particular surgical instrument includes a tubular housing 212 with a pivotably hinged jaw 216 disposed at the distal end of tubular housing 212. A needle 218 is removaby receivable by an aperture in jaw 216. A suture 220 is attached to the end of needle 218 and the remaining length of suture 220 is disposed along the longitudinal axis of tubular housing 212. Scale 100 is disposed near the distal end of tubular housing 212 and preferably covers the entire outer perimeter of tubular housing 212 so that graduations 110 are visible to the surgeon regardless of the orientation of surgical suturing apparatus 210.

In FIG. 7, yet another surgical suturing apparatus 310 is illustrated including scale 100 of the subject disclosure. As in previous embodiments, scale 100 is disposed near the distal end of a tubular housing 312. A suture 320 extends from the most distal end of tubular housing 312 with a needle 318 at the distal end of suture 320. Needle 318 and suture 320 are attached to a cartridge carrier 322 that is removably attached to tubular housing 312. It is preferred that scale 100 and graduations 110 are disposed such that graduations 110 encompass the entire outer perimeter of tubular housing 312 of surgical suturing apparatus 310.

Referring to FIG. 8, a different laparoscopic surgical instrument 510 is shown. Similar to previous instruments, it includes a tubular housing 512. Surgical instrument 510 has a grasping tool 514 at the distal end of tubular housing 512. This instrument permits the surgeon to grasp a suture 520 and determine the length of the unused portion. Once again, scale 100 is disposed along the distal end of tubular housing 512 just posterior to grasping tool 514. Having scale 100 disposed in this location permits the surgeon to determine the length of suture 520 accurately by moving suture 520 with grasping tool 514 along the side of tubular housing 512 to measure the length of suture 520. It is preferred that scale 100 and graduations 110 cover the outer perimeter

of tubular housing 512 so that the surgeon can view graduations 110 without having to reposition surgical instrument 510.

It will be understood that various modifications may be made to the embodiments disclosed herein. For example, the unit may be color coded to indicate the range and units of measurement. When supplied as part of a kit, it is fully compatible with other laparoscopic surgical instruments such as scissors, knot-tying tools, and other tools. Further still, other methods for disposing measuring structures on surgical instruments such as shrink-wrapping may be employed. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Those skilled in the art will envision other modifications within the scope and spirit of the disclosure.

The foregoing is considered illustrative only of the principles of the measuring apparatus. Further, this is not intended to be limited to the exact structure, construction and operation shown and described.

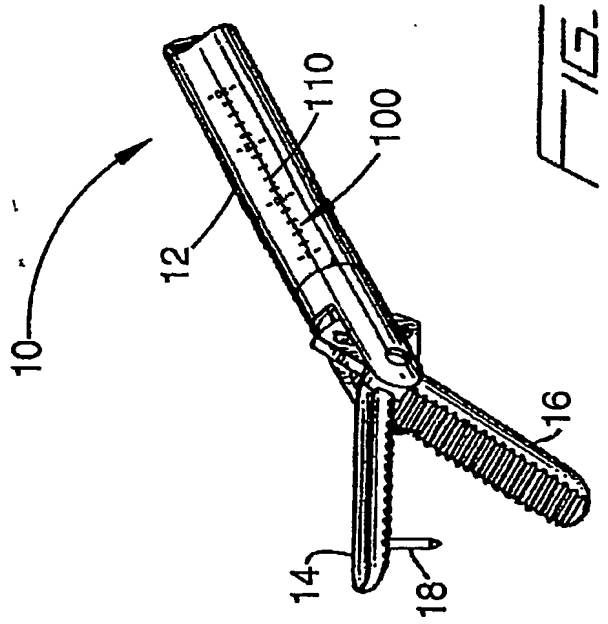


FIG. 1

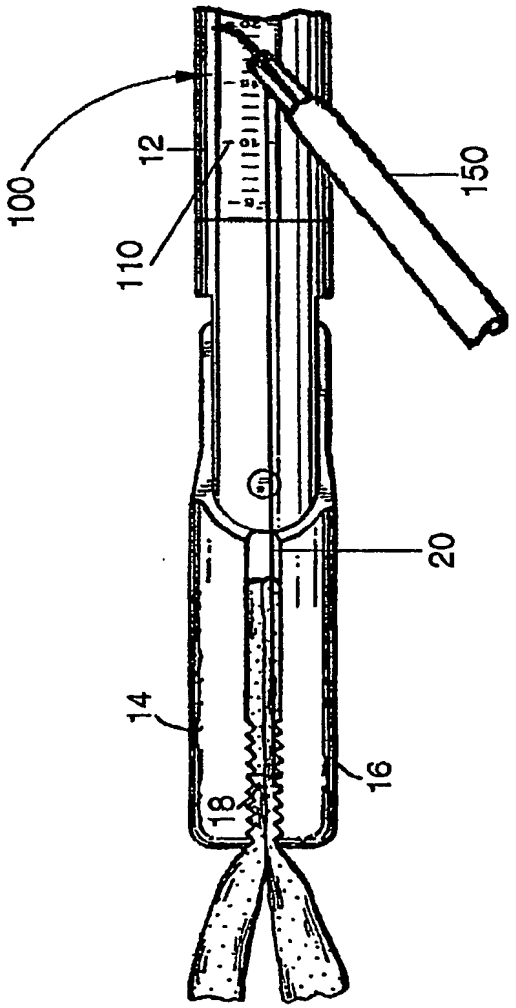


FIG. 2

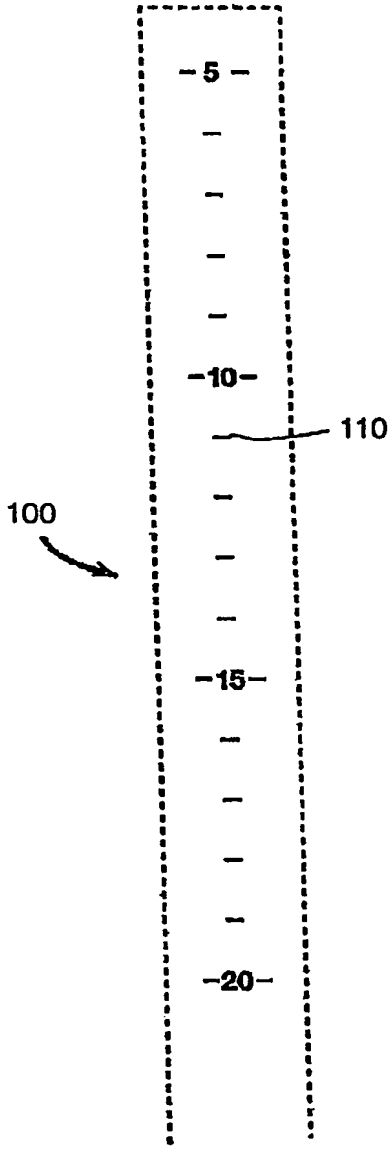


FIG. 3

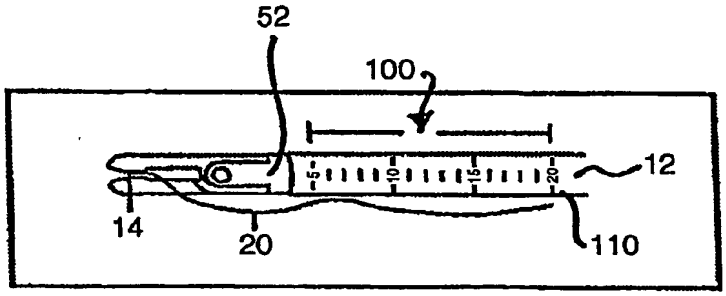


FIG. 4

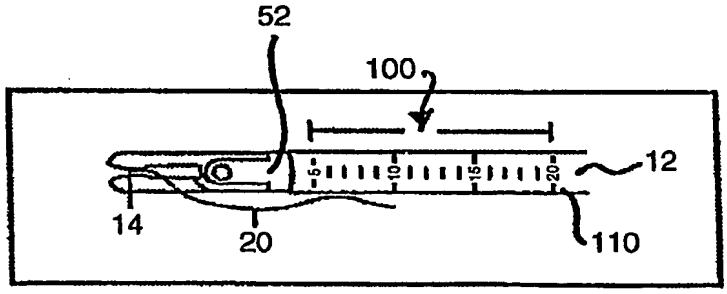


FIG. 5

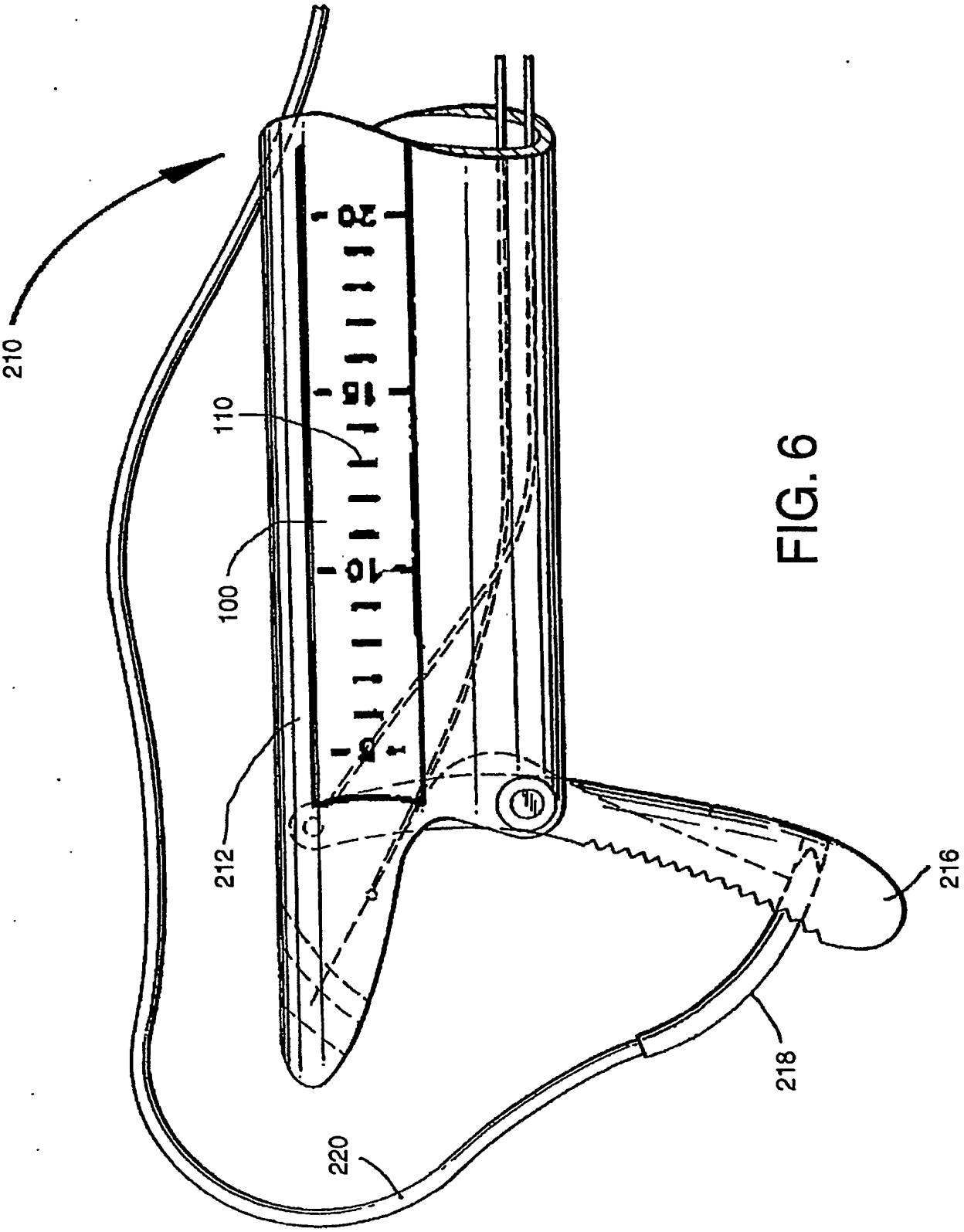


FIG. 6

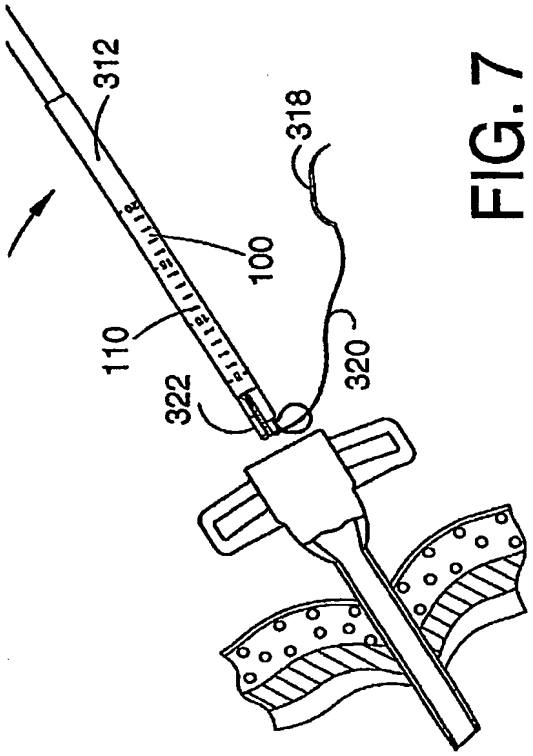


FIG. 7

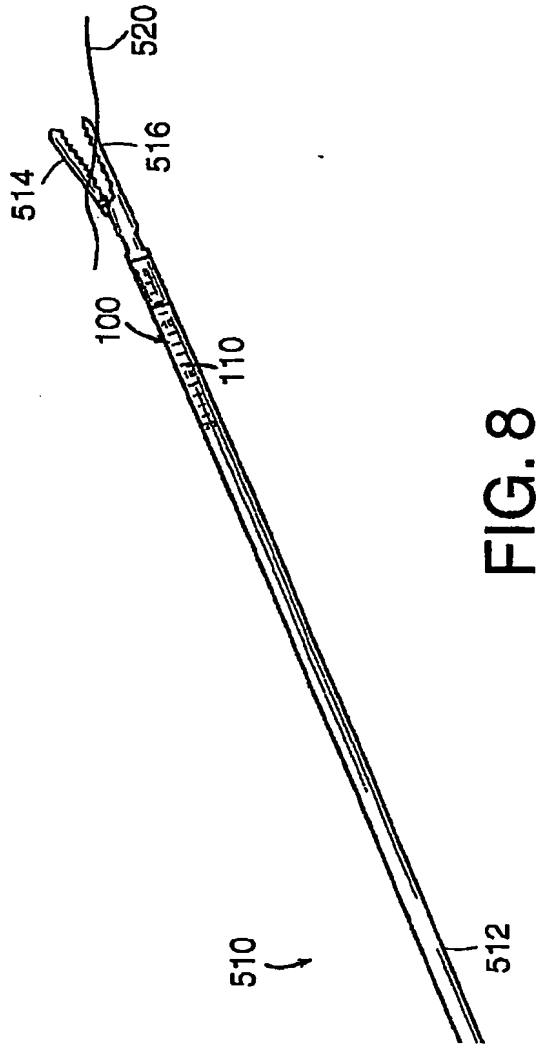


FIG. 8